

REMARKS

In the Office Action mailed March 10, 2005, in the above identified pending application, the examiner finally rejected applicants' claims 1-3, 7-16 and 42-53 for alleged anticipation or obviousness, with primary reliance upon the newly cited Feree reference, U.S. Publication US2004/0024462. In addition, the examiner objected to the "part-cylindrical" language appearing in dependent claim 52. The examiner also requested cancellation of the nonelected claims 4-6 and 17-41.

In response, applicants have canceled the nonelected claims 4-6 and 17-41. Cancellation of these nonelected claims is without prejudice to pursuing the subject matter thereof in one or more timely filed divisional applications.

In addition, by this Response, applicants have edited the language of dependent claim 52 to delete use of the phrase "part-cylindrical", as requested by the examiner.

Finally, by this Response, applicants submit herewith a Declaration Under 37 CFR 1.131, for purposes of antedating the cited Feree Publ. reference.

In this regard, claims 1-3, 7-16 and 42-53 of this application now stand rejected for anticipation or obviousness, with primary reliance upon the cited Feree Publ. reference, published February 5, 2004, and claiming the benefit of a prior-filed provisional application filed April 12, 2002. By contrast, the present utility application was filed December 15, 2003, and is based upon and claims the benefit of a prior-filed provisional application filed December 17, 2002. The February 5, 2004 publication date of the Feree reference is, quite clearly, subsequent to applicants' filing date.

The accompanying Declaration Under 37 CFR 1.131, signed by all three co-inventors in the present application, clearly demonstrates conception of a key aspect of the claimed invention, namely, the provision of "at least one" bearing seat in a total disc replacement (TDR) or implant characterized by "a generally part-circular cross sectional shape defined by laterally spaced-apart offset radii to include a generally flattened base

segment interposed between a pair of curved sides" – all as recited in applicants' independent claims 1 and 42. Exhibits 1 and 2 attached to the Rule 131 Declaration are hand-prepared drawings and related notes made by the co-inventors (Dr. Khandkar and Dr. Lakshminarayanan, respectively) on February 26 and 28, 2002, respectively – both dates prior to the earliest effective filing date (April 12, 2002) attributable to the Feree publication. Both documents (Exhs. 1 and 2) were made in Salt Lake City, Utah, in connection with preparation for a meeting with the other named co-inventors in connection with the "TDR Concept" or "TDR Design" then under development at Amedica Corporation – the assignee of the present application.

As stated in the Rule 131 Declaration, Exhibit 1 (two pages, prepared "2/26/02) illustrate the total disc replacement in one preferred form to include upper and lower end plates having convex articulation surfaces and each adapted for affixation to adjacent patient bone by means of porous bone ingrowth surfaces (porous CSC), together with an intermediate "bi-concave insert". Thus, Exh. 1 shows the total disc replacement having two articulatory interfaces, namely, a first interface between the upper end plate and the upper surface of the bi-concave insert, and a second interface between the lower end plate and the lower surface of the bi-concave insert. Page 1 of Exh. 1 shows these components in an anterior-posterior (A-P) view, whereas page 2 of Exh. 1 shows these components in a medial-lateral (M-L) view.

Exhibit 2 attached to the Rule 131 Declaration bears the date "Feb. 28, 2002". Exh. 2 (one page) outlines a concept for the specific geometry of the articulation interfaces for the "TDR Design", namely, the articulation interfaces shown in Exh. 1. Specifically in the medial-lateral (M-L) view as shown in Exh. 2, the above-noted "offset radii" concept is illustrated "to allow translation". This offset radii concept was and is designed to accommodate a limited degree of axial rotation between the engaged components, such as on the order of about +/- 6 to 10 degrees as noted on the exhibit.

As stated further in the Rule 131 Declaration, the co-inventors proceeded from February 28, 2002 with substantially continuous and on-going development activity on the total disc replacement (TDR) project

leading, *Inter alia*, to the filing of their provisional patent application a few months later on December 17, 2002.

Applicants' independent claims 1 and 42 were amended by the prior Response filed November 22, 2004, to recite this offset radii concept. As a result of such revision to applicants' independent claims 1 and 42, the examiner has newly cited the Feree Publ. Reference which is alleged to show this claimed offset radii concept. See Office Action, p. 3, lines 8-11.


Accordingly, the accompanying Declaration Under 37 CFR 1.131 is provided for purposes of antedating the newly cited Feree reference with respect to this key offset radii concept. Submission of this Rule 131 Declaration at this time, after final rejection, is proper since the Feree reference has not previously been cited in this case.

Conclusion

In conclusion, in view of the accompanying Declaration Under 37 CFR 1.131, together with the revision to dependent claim 52 and the cancellation of the nonelected claims, the remaining claims 1-4, 7-16 and 42-53 are believed to be in proper form for allowance. A formal Notice of Allowance is believed to be in order and is respectfully requested.

Respectfully submitted,

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